

EXHIBIT G

Mesh removal following sling/mesh placement: a multicenter study

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Introduction: Synthetic mesh utilized in the treatment of stress urine incontinence (SUI) and pelvic organ prolapse (POP) can often result in patients with postoperative mesh complications. Complications most often cited include: pain, mesh erosion into viscus organs, mesh extrusion into the vaginal epithelium, and infections. Patients are often treated with surgery for mesh and scar revision as well as mesh removal in an attempt to address complications. Patients who have surgery to remove the mesh are subjected to the risk of a new surgery as well as the potential complications of removing the mesh. At our institutions, we have a high volume of patients with mesh related complications who have undergone surgical mesh removal..

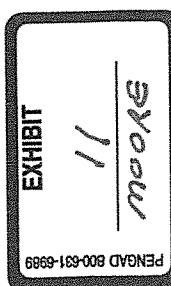
Objectives: The objective of this study is: 1) to determine the most common indications for mesh removal 2) to determine the most common complications attributed to the surgical mesh and 2) evaluate the incidence of surgical complications associated with the removal of a specific type of mesh sling and POP mesh.

Methods: This was a retrospective chart review of all patients who underwent surgical removal of synthetic materials from previous suburethral sling, transvaginal mesh, and sacrocolpopexy for mesh related complications from 2011 to 2013 at three tertiary referral centers in the Southeast United States. We included all women who underwent mesh/sling removal. The database was queried to identify potential subjects. Data was analyzed by using chi-square test for categorical data, and Student's t-test and Wilcoxon Rank Sum test for continuous data.

Results: A total of 445 patients with complications underwent mesh removal either laparoscopically, via groin dissection and/or transvaginally during the study period. There were a total of 506 mesh products removed. The mean patient age was 53.8 ± 11.2 year and parity 2.5 ± 1.2 . The majority of patients were caucasian (82.0%), postmenopausal (72.8%), sexually active (52.1%), and insured (76.4%). 82.9% had previous hysterectomy and 92.6% had previously been seen by a different physician(s). Twenty-five percent of patients were current smokers. Twenty-eight percent had previous surgery for sling/mesh revision or removal.

Of the 445 patients, 373 (83.3%) had a synthetic midurethral sling for SUI, 178 (40%) had transvaginal mesh and 38 (8.5%) had a sacral colpopexy inserted for treatment of POP. These slings can be categorized into retropubic slings (RP), transobturator (TOT) slings and single incision slings (SIS). The transvaginal mesh are categorized into anterior vaginal wall mesh and posterior vaginal wall mesh. The most common indications for sling and mesh revision/removal were pain, dyspareunia, pressure symptoms, erosion/extrusion, and vaginal discharge (Table 1). Of the 506 mesh products removed, 56.5% were slings and 43.5% were mesh for POP. Among the three types of synthetic slings, TOT was the most common type of sling removed. TOT group was 60% more likely to have pain than RP (OR 1.6, 95% CI 0.9-2.7).

Patients with sling who complained of vaginal pain with or without intercourse were subjected only to a vaginal approach to surgical removal of the sling (86.6%). Patients with lower abdominal /suprapubic



pain and vaginal pain that had a RPS underwent a vaginal and laparoscopic approach to sling removal (18.4%). Patients who complained of vaginal and groin pain that had a TOT sling underwent a vaginal and inguinal approach to sling removal (4.3%).

For patients requiring vaginal wall mesh removal, 42.3% of the patients had mesh removal from the anterior vaginal wall only, 30.6% posterior vaginal wall only and 14.0% both anterior and posterior mesh. Finally 13.1% of patients had sacral colpopexy mesh removed.

Complications encountered during the removal are as follow: The median intraoperative estimated blood loss was 50 cc. (range 0-800). 2 (0.5%) of patients required blood transfusions both were the result of laparoscopic TVT sling removal. Three patients had urethral injury all occurred during TOT sling removal, 2 ureteral injury both occurred during anterior vaginal wall mesh removal and 2 rectal injuries both during posterior vaginal wall mesh removal.

Conclusion: In our study, the most common indication for mesh removal was pain; however, the indication of mesh removal did not influence the mesh removal complication rate. Transvaginal sling revisions had the least amount of postoperative or intraoperative complications. Laparoscopic RP removal had the highest incidence of blood transfusion, Anterior vaginal wall mesh removal had the highest incidence of ureter injury rate, and posterior vaginal mesh removal had the highest incidence of rectal injury rate. Overall sling, transvaginal mesh and laparoscopic sacral colpopexy mesh removal are safe procedures in experienced hands.

Keyword: sling complication, mesh complication, mesh removal

Table 1- Top 5 indications for sling/mesh removal for sling and POP group, n (%)

Indication	Sling, n=309*	POP, n=215
1. Pain	184 (59.6)	120 (55.8)
2. Dyspareunia	40 (12.9)	26 (12.1)
3. Pressure symptoms	12 (3.9)	12 (5.6)
4. Erosion/ extrusion	7 (2.3)	11 (5.1)
5. Vaginal discharge	6 (1.9)	10 (4.7)

*include sling revision

Table 2- Type of sling/mesh removed (n=506)

Type of sling/mesh removed	N (%)
Sling	286 (56.5)
- Retropubic sling	106 (20.9)
- Transobturator tape	113 (22.3)
- Single incision sling	44 (15.4)
- Unidentified sling	5 (1.7)
Mesh for POP treatment	220 (43.5)
- Transvaginal mesh and kit	189 (37.35)
- Sacrocolpopexy/hysteropexy	29 (5.7)